

The Diabetes Pearl: diabetes biobanking in the Netherlands

Submission date 16/12/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 06/01/2017	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 04/01/2017	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Patients with type 2 diabetes have a high risk of cardiovascular (heart) disease and other complications which reduce their quality of life and require high levels of healthcare. The aim of this study is to examine the risk factors for diabetes complications, including biomarkers (molecules that can be measured in blood or tissue) and genetic information.

Who can participate?

Patients with type 2 diabetes in the Netherlands

What does the study involve?

Participants are asked permission to use their medical data for scientific research. The following information is collected: personal information, medication use, physical examination (body measurements, blood pressure, electrocardiography [heart electrical activity], retina [eye] photographs, vibration perception), questionnaires (socio-economic status, lifestyle, [family] history of disease, and well-being), and laboratory measurements. Participants also contribute urine and blood samples and DNA for genetic analysis. National databases like the municipality register are used for mortality (death rate) follow-up.

What are the possible benefits and risks of participating?

There is no direct benefit for the participants. In the future, the study results may lead to improvements in diabetes care. There are no risks of participating.

Where is the study run from?

VU University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?

November 2006 to January 2050

Who is funding the study?

1. Dutch Ministry of Health, Welfare and Sport (Netherlands)
2. Dutch University Hospitals (Netherlands)

Who is the main contact?

Dr Petra Elders

Contact information

Type(s)

Scientific

Contact name

Dr Petra Elders

Contact details

Department of General Practice and Elderly Care

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

The Diabetes Pearl: diabetes biobanking in the Netherlands - an observational prospective cohort study

Study objectives

Type 2 diabetes is associated with considerable comorbidity and severe complications, which reduce quality of life of the patients and require high levels of healthcare. The Diabetes Pearl is a large cohort of patients diagnosed with type 2 diabetes, covering different geographical areas in the Netherlands. The aim of this study is to create a research infrastructure that will allow the study of risk factors, including biomarkers and genetic determinants for severe diabetes complications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the VU University Medical Center, 09/07/2009, ref: NL27783.029.09

Primary study design

Observational

Study design

Observational prospective cohort study

Study type(s)

Other

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Baseline examinations were performed November 2009 - November 2016. To ensure quality of the data collected, standard operation procedures were developed and used in all 8 recruitment centers. From all patients who provide informed consent, the following information is collected: personal information, medication use, physical examination (anthropometry, blood pressure, electrocardiography (ECG), retina photographs, ankle-brachial index, peripheral vibration perception), self-report questionnaire (socio-economic status, lifestyle, (family) history of disease, and psychosocial well-being), laboratory measurements (glucose, A1c, lipid profile, kidney function), biobank material (storage of urine and blood samples and isolated DNA). Follow-up of morbidity and mortality is planned through medical care providers and municipal registries. All gathered clinical data and biobank information is uploaded to a database for storage on a national level. Biobanks are maintained locally at all recruitment centers.

Intervention Type

Other

Primary outcome(s)

Diabetes complications and mortality:

1. Cardio-metabolic risk factors, assessed by anthropometry, blood pressure, ECG, ankle-brachial index, laboratory measurements, and self-report questionnaire at baseline
2. Retinopathy, assessed by retinal photography at baseline
3. Nephropathy, assessed with laboratory measurements at baseline
4. Neuropathy, assessed by peripheral vibration perception at baseline

Follow-up visits have not been planned yet. Follow-up of morbidity and mortality is done through medical care providers and municipal registries.

Key secondary outcome(s)

Quality of life and physical functioning, assessed by self-reported questionnaire at baseline

Completion date

01/01/2050

Eligibility**Key inclusion criteria**

1. Patients with type 2 diabetes mellitus according to WHO criteria
2. Treated by a Dutch University Clinic, an associated primary care clinic or transmural care system

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

All

Key exclusion criteria

None

Date of first enrolment

01/11/2009

Date of final enrolment

01/11/2016

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 HV

Sponsor information**Organisation**

VU University Medical Center

ROR

<https://ror.org/00q6h8f30>

Funder(s)**Funder type**

Government

Funder Name

Ministerie van Volksgezondheid, Welzijn en Sport

Alternative Name(s)

Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Funder Name

Dutch University Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

Data will not be made available. Proposals for collaborative research can be submitted to Dr Petra Elders.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/11/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes